PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

FENSTER, Paul
Fenster & Company, Intellectual Property 2002
P. O. BOX 10256
49002 Petach Tikva
ISRAEL

Date of mailing *(day/month/year)* 19 January 2006 (19.01.2006)	
Applicant's or agent's file reference 227/04057	IMPORTANT NOTICE

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/000619	09 July 2004 (09.07.2004)	09 July 2003 (09.07.2003)

Applicant
GLUCON INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Simin Baharlou
Facsimile No. +41 22 740 14 35	Facsimile No. +41 22 338 71 30

Form PCT/IB/326 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 227/04057	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2004/000619	International filing date *(day/month/year)* 09 July 2004 (09.07.2004)	Priority date *(day/month/year)* 09 July 2003 (09.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant GLUCON INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 09 January 2006 (09.01.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Simin Baharlou
Facsimile No. +41 22 740 14 35	Telephone No. +41 22 338 71 30

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

20/1

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WIPO PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/000619	09.07.2004	09.07.2003

International Patent Classification (IPC) or both national classification and IPC
A61B5/00

Applicant
GLUCON INC.

1. This opinion contains indications relating to the following items:

   - ☒ Box No. I Basis of the opinion
   - ☒ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

   If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

   If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

   For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Martelli, L

Telephone No. +49 89 2399-7416

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-10,16
	No: Claims	1,2,11-15,17
Inventive step (IS)	Yes: Claims	3-8
	No: Claims	1,2,9-17
Industrial applicability (IA)	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

1 CITED DOCUMENTS

Reference is made to the following documents, cited in the International Search Report:

D1: US-B-6 587 703 (CHENG XUEFENG ET AL) 1 July 2003 (2003-07-01)
D2: US-A-6 061 583 (ASANO KAORU ET AL) 9 May 2000 (2000-05-09)
D3: US-A-5 360 004 (WIGGINS ET AL) 1 November 1994 (1994-11-01)
D4: US 2003/109772 A1 (MILLS ALEXANDER K) 12 June 2003 (2003-06-12)
D5: US 2002/141714 A1 (REED W A ET AL) 3 October 2002 (2002-10-03)

2 ARTICLE 33 PCT

The application does not meet the requirements of Article 33 PCT because the subject matter of claims 1, 2,11 to 15 and 17 is not new in the sense of Article 33(2) PCT and the subject matter of claims 9, 10 and 16 does not involve and inventive step in the sense of Article 33(3) PCT.

2.1 Independent claim 1 (D1)
Dependent claims 11, 14

D1 describes an apparatus for assaying an analyte in blood in a blood vessel below a patient's skin (see column 9, line 66, to column 10, line 6), the apparatus comprising:
- two light sources (S1, S2, see column 11, line 11) controllable to transmit light into tissue below the skin through at least one first region on the skin;
- two light detectors (D1, D2, see column 11, line 12) that receive a portion of the transmitted light that reaches at least a second region on the skin after propagating through the blood vessel and generates signals responsive to the received light;

- a controller (see column 26, lines 37-38; the fact the "control switches" command the operation of components of the device implies the presence of such a "controller");

wherein the controller controls the two (single) light sources to transmit light at one wavelength that interacts with blood and at one wavelength that interacts with the analyte (see column 13, lines 16-17, and column 26, line 37, wherein, of the two wavelengths λ1 and λ2, one interacts with oxyhaemoglobin (considered as the "blood") and the other with deoxyhaemoglobin (here considered as the "analyte") and uses the signals responsive to the light that interacts with the blood to determine a location for the blood vessel and the determined location and signals responsive to the light to assay the analyte ("two-dimensional distribution of blood volume and oxygen saturation", see column 26, lines 30-31).

Hence D1 discloses all the features of claims 1, 11, 14; these claims are therefore not new (Article 33(2) PCT).

2.2 Independent claim 1 (D2)
Dependent claims 11, 12, 14

Claim 1 is also not new (Article 33(2) PCT) with reference to D2 because this documents discloses a blood analyte concentration apparatus (see column 5, line 65) comprising two light sources (11a, 11b, see column 6, lines 28-30), a CCD detector (15, see column 5, line 67 to column 6, line 1, and column 6, line 28), the light source being controlled to transmit light at one wavelength interacting with blood (e.g., with haematocrit, see column 6, lines 43-48 and column 7, lines 27-29) and at another wavelength interacting with a blood analyte (e.g., haemoglobin, see column 7, lines 38-43), the detected light being used to determine a location of the blood vessel (see column 6, lines 60-61, and column 8, lines 7-14) and to assay the analyte (also using the detected location, see column 8, lines 17-18, and column 8, lines 28-30).

Hence not only claim 1 is not new with reference to D2, but also dependent claims 11, 12 and 14.

2.3 **Dependent claims 2, 13, 15**

D1 and D2 further disclose the following features:

Claim 2: light transmission between two different pairs of locations of source and detectors, the distance between source and detector of one pair being different from the distance between source and detector of the other pair (see D1, column 21, lines 32-34, and column 21, lines 61-63).
Claim 13: lens focussing detected light on the CCD (14, see D2, column 6, line 20).
Claim 15: movable light source (see D1, column 23, lines 24-26).

These claims are therefore not new (Article 33(2) PCT).

2.4 **Dependent claims 9, 10, 16**

The following features of dependent claims 9, 10 and 16 are disclosed, in combination with the remaining features, neither in D1 nor in D2. These claims, however, are considered as not involving an inventive step (Article 33(3) PCT) because the same features are described in other blood analyte detecting device as providing the same advantages as in the present application:

Claims 9, 10: light pipes for transmitting light between one light emitter and the skin as well as between the skin and one detector (see D3, abstract and figure 1).
Claim 16: detect glucose concentration (whereas D1 only discloses that, by choosing an appropriate wavelength, the concentration of other chromophores such as lipids, water and cytochromes can be measured, D4, see paragraph 326, suggests to use light of different wavelengths to detect glucose concentration).

2.5 **Dependent claims 3-8**

The subject-matter of dependent claim 3 differs from D1 and D2 in that the blood analyte detecting apparatus further comprises an apparatus for modulating the blood flow through the blood vessel under examination.

The subject-matter of claim 3 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be considered as to provide means to facilitate the identification and the location of irradiated blood vessels by provoking a characteristic perturbation on the blood vessel.

The solution to this problem, as proposed in claim 3, is considered as involving an inventive step because the apparatus of D1 and D2 do not deal with any means for modulating blood flow. D5 discloses a system for evaluating a characteristic of a sample by light irradiation, the system comprising a modulator (an acousto-optical modulator, see paragraph 38) which allows to detect the velocity of blood particles; this modulator would not lead to the device of claim 3 if used on the apparatus of D1 or D2.

Claims 4 to 8 are dependent on claim 3 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

2.6 Independent claim 17

D1 describes a method for assaying an analyte in blood in a blood vessel below the skin (see column 9, line 67 to column 10, line 2), the method comprising:
- transmitting light at one wavelength that interacts with blood and at one wavelength that interacts with the analyte (see column 13, lines 16-17, and column 26, line 37, wherein, of the two wavelengths $\lambda 1$ and $\lambda 2$, one interacts with oxyhaemoglobin (considered as the "blood") and the other with deoxyhaemoglobin (here considered as the "analyte");
- generating signals responsive to a portion of the transmitted light at both wavelengths that reaches the skin after propagating through the blood vessel (see column 11, lines 11-13);
- using the signals responsive to the light that interacts with the blood to determine a location for the blood vessel and the determined location and signals responsive to the light to assay the analyte ("two-dimensional distribution of blood volume and oxygen saturation", see column 26, lines 30-31).

Hence D1 discloses all the features of claim 17; this claim is therefore not new (Article 33(2) PCT).